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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/146,783	09/03/1998	NICHOLAS JOHN DEACON	9606Z-IY	9825

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EXAMINER	
PARKIN, JEFFREY S 22	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application N .	Applicant(s)	
	09/146,783	DEACON ET AL.	
	Examin r	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Jeffrey S. Parkin, Ph.D.*.

(2) *James C. Housel, SPE, 1648*.

(3)*Frank S. DiGiglio (Reg. No. 31,346)*.

(4)*Xiaochun Zhu*.

Date of Interview: *18 March 2003* .

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____ .

Claim(s) discussed: *all pending claims* .

Identification of prior art discussed: _____ .

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See.Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants' representatives requested rejoinder of the non-elected claims submitted in the last response pursuant to an earlier application with the Examiner. Applicants appear to have misunderstood the crux of the last interview. While the Examiner previously stated that he would consider claims directed toward immunogenic compositions and methods of immunization using said compositions, he was also expecting the vaccination claims to be canceled. Since the last response failed to do so and presented additional claims directed toward another invention, the claims were withdrawn from further consideration. However, Applicants' representatives were advised that as a courtesy and to facilitate the expeditious prosecution of the application, the claims would be rejoined upon receipt of the next amendment. However, applicants were also advised that several independent and distinct inventions were present (i.e., multiple methods and products) and that restriction may be required in future applications presenting similar groups of claims. Applicants requested further clarification vis-à-vis the enablement requirements for HIV vaccines. The basis of the enablement rejection pertaining to HIV-1 and -2 vaccines and therapeutics have been clearly set forth in previous Office actions. To date, the state-of-the-art vis-à-vis HIV vaccine development is one of failure and unpredictability. This is due to several factors, including inter alia, the lack of adequate animal models with which to assess human vaccine efficacy, the lack of understanding pertaining to the correlates of protective immunity, and the quasisspecies nature of HIV infection. Additional caveats have been presented pertaining to the administration of a replication-impaired HIV-1 nef mutant to human subjects in an attempt to induce protective immune responses. Applicants' representatives were further advised that claims simply directed toward immunogenic compositions comprising the HIV-1 nef-deletion mutants would overcome the enablement issues. However, prior art might be applicable. Claims reciting immunization methods still presented enablement issues because the disclosure only appears to support claims directed toward the treatment and prevention of HIV-1 infection. The specification does not appear to support other applications. For instance, the skilled artisan would not normally consider immunizing a human subject with a replication-impaired HIV-1 construct of reduced pathogenicity simply for the purposes of generating and recovering antisera. However, the disclosure may support other immunization applications that would not be subject to the same enablement criteria as vaccine claim language. For instance, the disclosure may support the immunization of macaques or rabbits with the claimed compositions to generate antisera that would prove useful as diagnostic reagents. It was suggested that applicants' representatives peruse the disclosure to see if additional support exists for applications other than HIV-1 vaccine development.